Decision Memo for Glycated Hemoglobin/Glycated Protein (Addition of CPT Code 83037, Hemoglobin; glycosylated [A1c] by device cleared by FDA for home use) (CAG-00373N)

Decision Summary

CMS has determined CPT code 83037, Hemoglobin; glycosylated (A1c) by device cleared by FDA for home use— does not flow from the existing narrative for conditions for which a glycated hemoglobin is reasonable and necessary. We shall not add CPT code 83037 as a HCPCS code encompassed under the national coverage determination (NCD) on glycated hemoglobin/glycated protein testing at section 190.21 of the Medicare National Coverage Determination Manual (NCDM).

Back to Top

Decision Memo

This coding analysis does not constitute a national coverage determination (NCD).

TO: Administrative File: CAG – 373N Addition of CPT code 83037, Hemoglobin; glycosylated (A1c) by device cleared by FDA for home use—as a HCPCS code encompassed under the national coverage determination (NCD) on glycated hemoglobin/glycated protein testing at section 190.21 of the Medicare National Coverage Determination Manual (NCDM).

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SUBJECT: Addition of CPT code 83037, Hemoglobin; glycosylated (A1c) by device cleared by FDA for home use—as a HCPCS code encompassed under the national coverage determination (NCD) on glycated hemoglobin/glycated protein testing at section 190.21 of the Medicare National Coverage Determination Manual (NCDM).

DATE: April 2, 2007

I. Decision

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II. Background

Glycosylated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c (HbA1c, sometimes Hg A1C) refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. We use HbA1c in this document except when citing the work of others. Hg is the symbol for elemental mercury, and we wish to minimize the confusion for the lay public. The terms glycated and glycosylated also appear interchangeably in the literature and in the various coding references. Test kits have now been developed to permit HbA1c testing in physician offices and patient homes.

Glycosylated hemoglobin in whole blood assesses glycemic control over a period of 4-8 weeks and appears to be an appropriate test for monitoring a patient who is capable of maintaining long term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1-2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Test results are customarily reported as a percent, with values below 6% in normal individuals, and values that may reach close to 20% is individuals who have had sustained hyperglycemia. Glycosylation of hemoglobin is nonlinear during the lifespan of the red blood cell, with a greater effect from more recent levels of glycemia.

In contrast to home glucose measurement, where the patient may be instructed to change his dose of insulin by a specific amount in response to a home reading, the HbA1c result does not reasonably prompt an immediate or near term action by the patient. Instead, HbA1c results are properly interpreted by the treating physician in light of the patient’s glucose readings, medications, and concomitant medical conditions.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, these NCDs, including the NCD on glycated hemoglobin/glycated protein testing became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes That Do Not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities

On January 26, 2007, CMS, in response to an external request from Metrika, Inc, manufacturer of the Metrika A1cNow® for Home Use, opened a coding analysis item regarding the addition of CPT 83037 to the HCPCS code list encompassed under the national coverage determination (NCD) on glycated hemoglobin/glycated protein testing at section 190.21 of the Medicare National Coverage Determination Manual. We posted a tracking sheet (https://www4.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=201) and solicited public comment for 30 days on the appropriateness of adding code 83037.

We received 3 public comments during the comment period, one from the American Academy of Family Physicians (AAFP), one from the American Association of Clinical Endocrinologists (AACE), and one from The Endocrine Society. All three organization expressed support for office-based point of care (POC) testing in lieu of sending the specimen out to a laboratory and for having the test result available while the patient was in the office.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis

In considering the request to add CPT 83037, Hemoglobin; glycosylated (A1c) by device cleared by FDA for home use to the NCD, CMS considers whether the requested code flows from the NCD narrative. Thus, in this case, CMS considers whether testing using a device cleared by FDA for home use is fully consistent with the NCD.

We agree with the AAFP, AACE, and The Endocrine Society comments that point of care testing in the office, with test results available to guide the treating physician's treatment recommendation, can facilitate the clinical management of diabetes.

The HCPCS Codes list in the NCD currently includes the following:

82985 Glycated protein
83036 Hemoglobin, glycated (now referred to as Hemoglobin, glycosylated)

We note that 83036 does not specify the test location, i.e. it does not preclude point of service testing.

We are concerned that has been conflicting published information on the appropriate use of CPT 83037. The 2006 version of cpt® changes describes the reason for the addition of 83037, noting:

"…This testing platform may be used in a clinical setting to provide rapid turnaround Hg [*sic*] A1c levels as a means to enable physicians and other health care providers to manage glycemic control in people with diabetes…"

CPT 83037 is discussed in the Coding Communication: Changes to Pathology and Laboratory-Part 1 on page 7 of the February 2006/Volume 16, Issue 2 of cpt® Assistant.

"…CPT code 83037, Hemoglobin, glycosylated (A1C) by device cleared by FDA for home use, was established for reporting a glycosylated hemoglobin (A1C) test that is obtained in the patient's home with a Food and Drug Administration (FDA) cleared device…"

CPT 83037 is also discussed in the Coding Consultation: Questions and Answers section on page 15 of the October 2006/Volume 16, Issue 10 of cpt® Assistant.

"Question: Is CPT code 83037 intended to report A1C test results obtained in the patient's home?

AMA Comment: CPT code 83037 is not intended to report a glycosylated hemoglobin (A1C) test that is obtained in the patient's home by the patient or family. Rather, code 83037 is intended to report rapid result testing for Hg [*sic*] A1C levels to assist the physician in the management of glycemic control in the patient with diabetes while the physician is present with the patient. Code 83037 is reported for testing and interpretation of results during a patient encounter using a device cleared by the FDA for home use."

We want to emphasize that Medicare does not pay for glycosylated hemoglobin testing as a clinical laboratory test if the test is performed by the patient or the patient's family. All Medicare requirements pertinent to clinical laboratory services must be fully met.

We are also concerned that the existence of several similar Metrika tests may cause confusion about the correct coding of claims. CMS is aware of several Metrika A1C tests that have received FDA 510(k) clearance.

A1cNow for professional use	K020235	cleared 2/15/02
A1cNow for Rx home use	K020234	also cleared 2/15/02
A1cNow for home use (direct to consumer use)	K022661	cleared 12/13/02
InView	K051321	cleared 6/13/05

Summary

We believe that point of care testing supports the efficient management of diabetes by treating physicians. The availability of test results during the office visit can reduce or eliminate the need for followup telephone contact, which in practice often entails several calls between the patient and the physician and possibly the pharmacy. However, as we noted above, the current NCD does not prevent point of care testing.

There has been apparent confusion regarding the appropriate use of CPT 83037, evidenced by the February 2006 and October 2006 cpt® Assistant. Medicare does not generally pay for clinical laboratory testing performed by the patient or family. We conclude that the current understanding of code CPT 83037 is imprecise, and that its inclusion in the HCPCS table of this NCD could lead to confusion and to the submission of claims to Medicare for services that are not Medicare benefits.

Therefore, we do not believe that the addition of this code flows from the narrative of the NCD and we will not use the CAL process to add this code to the covered code list. We believe that the addition of CPT code 83037 would represent a substantive change to the NCD and that the evidence relevant to the requested addition would appropriately be reviewed in an NCD reconsideration.

Back to Top

Bibliography

Kilpatrick E. Glycated haemoglobin in the year 2000. *J Clin Pathol* 53:335–339, 2000.

Back to Top